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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,304	08/21/2003	Samuel I. Stupp	126481.01001	8011

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,304	STUPP ET AL.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 29, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *22-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on March 29, 2006.

Claims 1-40 are pending in the application.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Claims 1-21 are presented for examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forns et al. (Biopolymers, 2000) in view of Fields et al. (Biopolymers 1998) and in

view of Torchilin (J Cont Rel, 2001), as evidenced by Amino Acid Structures at Physiological pH, http://www.brynmawr.edu/Acds/Chem/mnerzto/amino_acids.htm.

Forns et al. teach a peptide amphiphile composition comprising:

a hydrophobic component having a single alkyl group; and

a hydrophilic component covalently bonded to said hydrophobic component in said peptide amphiphile, said hydrophilic component having a net charge at physiological pH. Please note that, e.g., C_{12}-(Gly-Pro-Hyp)$_4$-[Gly-Val-Lys-Gly-Asp-Lys-Gly-Asn-Pro-Gly-Trp-Pro-Gly-Ala-Pro-(Gly-Pro-Hyp)$_4$-NH_2 (see, e.g., Table III) inherently has a positive net charge at physiological pH [based on the individual charges of each amino acid at physiological pH as evidenced by: Amino Acid Structures at Physiological pH, accessed online 6/5/06 at http://www.brynmawr.edu/Acds/Chem/mnerzto/amino_acids.htm].

Forns et al. also teach that such mono-alkyl peptide amphiphiles (e.g., Table III) would tend to self-assemble as micelles and that the aggregation of peptide-amphiphiles such as C_{12}-(Gly-Pro-Hyp)$_4$-[Gly-Val-Lys-Gly-Asp-Lys-Gly-Asn-Pro-Gly-Trp-Pro-Gly-Ala-Pro-(Gly-Pro-Hyp)$_4$-NH_2 shows very similar behavior to that for the micelle aggregation size for alkyl betaines in water (e.g., page 453, column 2, lines 6-27).

Forns et al. do not teach a mono-alkyl peptide amphiphile with inherently has a negative net charge at physiological pH nor do they teach adding an agent for inducing micelle formation.

Fields et al. teach a negatively charged monoalkyl peptide-amphiphile (e.g. page 147, column 2, lines 6-11 and Figure 1B). Fields et al. does not teach adding an agent to induce micelle formation.

Torchilin teaches that micelle formation may be induced by agents such as removal of solvent and electrolytes (page 139, column 2; page 140, column 1, lines 1-2, Figures 1 and 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to create self-assembling micelles from the compositions of Forns et al. and Fields et al. as taught by Forns et al. (e.g., page 544, column 2, lines 13-23) . The skilled artisan would have been motivated to do so because mono-alkyl peptide-amphiphiles can be utilized to create a variety of protein-like molecular architectures wherein the alkyl chain enhances stability of the structural element and induces aggregates of defined sizes (e.g., Forns, abstract). There would have been a reasonable expectation of success, because it was known that monoalkyl hydrocarbon tails tend to associate to form peptide micelles as taught by Forns et al. (e.g., page 543, column 2, lines 6-27; page 544, column 2, lines 13-23). The adjustment of particular conventional working conditions [e.g., determining appropriate net charge or amino acid composition (see, e.g., Fields et al. page 147, lines 1-4, page 150, lines 1- 22) and/or inducing formation of micelles with an agent such as solvent removal or an electrolyte (see, e.g., Torchilin, page 139, column 2; page 140, column 1, lines 1-2) within such peptide amphiphiles] is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Thus the invention as a

whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forns et al. (Biopolymers, 2000) in view of Fields et al. (Biopolymers, 1998), as evidenced by Amino Acid Structures at Physiological pH, http://www.brynmawr.edu/Acds/Chem/mnerzto/amino_acids.htm.

Forns et al., Fields et al. and http://www.brynmawr.edu/Acds/Chem/mnerzto/amino_acids.htm.are relied upon as above.

Forns et al. and Fields et al. do not expressly teach a peptide-amphiphile compound comprising:

An alkyl tail;

A structural peptide covalently bonded to said alkyl tail; and

A functional peptide covalently bonded to said structural peptide opposite said alkyl tail; said functional peptide having an overall conical shape and a net charge at a physiological pH.

Fields et al. teach that that monoalkyl peptide-amphiphiles may be used in the possible formation of bilayer membrane systems, where the lipid tail serves not only as a peptide structure-inducing agent but also as an anchor of the functional head group in the lipid assembly (page 150, columns 1-2).

Forns et al. teach aggregation of various geometric forms such as alpha-helical and triple-helical, but not conical.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Forns et al. and Fields et al. by creating a surface-coated peptide amphiphile as taught by Fields et al. The skilled artisan would have been motivated to do so because surface-coated peptide amphiphiles have been shown to promote cellular recognition and signaling (e.g., Forns et al. page 544, column 2, lines 32-48). There would have been a reasonable expectation of success, given several bilayer systems as such have been successfully implemented as taught by Fields et al. (e.g., page 150, columns 1-2). The adjustment of particular conventional working conditions [e.g., determining appropriate net charge or amino acid composition (see, e.g., Fields et al. page 147, lines 1-4, page 150, lines 1-22) and/or utilizing conical peptides within the instantly claimed peptide-amphiphile composition] is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/005,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are drawn to a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of Application '552.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/005,314. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are drawn to a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of Application '314.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/368,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are drawn to a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of Application '517.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,890,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions comprise a peptide amphiphile composition comprising a hydrophobic and a hydrophilic component bonded to said hydrophilic component having a net charge at physiological pH, said peptide amphiphile forming a micelle. Further, the instantly claimed composition encompasses and/or is encompassed by the composition of US '654.

Please note that, due to the large volume of related applications that Applicants encompassing similar subject matter, Examiner requests that Applicants indicate any other relevant applications containing overlapping claimed subject matter therein and that would therefore be object to double patenting rejections.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 06/06

6/25/08
ANISH GUPTA
PRIMARY EXAMINER